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BIOGEN
FOR THE RESULTS YOU WANT

SLOW RELEASE MAGNESIUM

PROFESSIONAL INFORMATION

D 34.7 Minerals. Complementary Medicine: Health Supplement.

Health supplements are intended only to complement health or supplement the diet.

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use. Health supplements are intended only to complement health or supplement the diet.

SCHEDULING STATUS: S0

1. NAME OF THE MEDICINE
BIOGEN SLOW RELEASE MAGNESIUM tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each BIOGEN SLOW RELEASE MAGNESIUM tablet contains:		%NRV*
Magnesium Sulphate Dihydrate	440,00 mg	19 %
Providing elemental Magnesium	68,40 mg	
Dicalcium Phosphate	230,00 mg	
Providing elemental Calcium	67,70 mg	5 %
Providing elemental Phosphorus	52,40 mg	4 %

*%Nutrient Reference Values (NRVs) for individuals 4 years and older (2010)
Contains sweetener (110 mg mannitol per tablet)
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Tablets

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
BIOGEN SLOW RELEASE MAGNESIUM contains magnesium which contributes to normal energy-yielding metabolism, normal electrolyte balance, and the maintenance of normal muscle and nervous system function. Calcium and phosphorus contribute to the development and maintenance of bones and teeth.

4.2 Posology and method of administration
Adults and children over 12 years of age:
Adults: Take three (3) tablets daily or as recommended by healthcare provider.
Elderly: No dose adjustment is necessary.
Patients with Renal Impairment: Magnesium is contraindicated in patients with severe renal impairment (see Section 4.3). There is no dose adjustment necessary in patients with mild to moderate renal impairment.

4.3 Contraindications
- If you have a hypersensitivity to the ingredients or any of the excipients listed in 6.1.
- If you have hypercalcaemia or hypercalciuria.
- If you have renal impairment.

4.4 Special warnings and precautions for use
Special care should be taken with BIOGEN SLOW RELEASE MAGNESIUM.
If you are taking any prescribed medication, please check with your healthcare provider before taking this medicine.
Please take note of the following:
- Use BIOGEN SLOW RELEASE MAGNESIUM with caution if you are taking magnesium containing antacids.
- Caution is advised in patients with renal impairment. Monitoring serum magnesium levels and the patient's clinical status is essential to avoid the consequences of over dosage in toxemia.
- Magnesium absorption may be reduced in patients who have undergone extensive bowel resection.
- In the case of confirmed magnesium deficiency, concomitant hypocalcaemia and hypokalaemia should be suspected and corrected if confirmed, since magnesium deficiency is frequently secondary to those conditions.
- The additive effect of concomitantly administered products containing mannitol and dietary intake of mannitol should be taken into account.

Nutritional supplementation should not replace a balanced diet. Do not exceed the recommended dose without consulting a healthcare provider.

4.5 Interaction with other medicines and other forms of interaction
Interactions with Medicines
- Use BIOGEN SLOW RELEASE MAGNESIUM with caution if you are taking magnesium containing antacids.
- Caution is advised in patients with renal impairment. Monitoring serum magnesium levels and the patient's clinical status is essential to avoid the consequences of over dosage in toxemia.
- Magnesium absorption may be reduced in patients who have undergone extensive bowel resection.
- In the case of confirmed magnesium deficiency, concomitant hypocalcaemia and hypokalaemia should be suspected and corrected if confirmed, since magnesium deficiency is frequently secondary to those conditions.
- The additive effect of concomitantly administered products containing mannitol and dietary intake of mannitol should be taken into account.

Interactions with Diseases/Impairments
- BIOGEN SLOW RELEASE MAGNESIUM and use in Haemophiliacs and patients scheduled for surgery are advised to discontinue use at least 2 weeks before elective surgical procedures (see section 4.4).
- Renal disease reduces magnesium excretion and increases the risk for hypermagnesemia. Use cautiously in individuals with reduced kidney function due to an increased risk of hypermagnesemia.

Interactions with Food
- Vitamins, minerals and nutrients obtained from other sources should be taken into account when prescribing / suggesting BIOGEN SLOW RELEASE MAGNESIUM.
- Caution is advised when magnesium is consumed together with excessive alcohol intake, this may lead to renal excretion.

4.6 Fertility, pregnancy and lactation
The safety and efficacy of BIOGEN SLOW RELEASE MAGNESIUM in pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines
Patients should exercise caution before driving or operating machinery until they are reasonably certain that BIOGEN SLOW RELEASE MAGNESIUM does not affect their performance.

4.8 Undesirable effects
Orally, BIOGEN SLOW RELEASE MAGNESIUM is well-tolerated.

4.8 a Summary of adverse reactions
Gastrointestinal disorders:
Frequent: gastrointestinal discomfort including flatulence, nausea and constipation.

4.8b Description of selected adverse reactions
BIOGEN SLOW RELEASE MAGNESIUM may cause gastrointestinal discomfort.

4.8 c Paediatric Population
Children: Below 9 years: Not recommended for children below the age of 9 years old. Consult a healthcare practitioner prior to use.
Children: 9 to 18 years: Take two to three (2-3) tablets daily. Do not exceed the recommended dosage.

4.8 d Other special populations
Patients with Renal Impairment: Magnesium is contraindicated in patients with severe renal impairment (see Section 4.3). There is no dose adjustment necessary in patients with mild to moderate renal impairment. No clinical data are available on the effects of BIOGEN SLOW RELEASE MAGNESIUM on other special populations.

4.8 e Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: *https://www.sahpra.org.za/Publications/Index/8.*

4.9 Overdose
See section 4.8.
In the event of overdose, treatment should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES
BIOGEN SLOW RELEASE MAGNESIUM, contains magnesium which contributes to normal energy-yielding metabolism, normal electrolyte balance, and the maintenance of normal muscle and nervous system function. Calcium and phosphorus contribute to the development and maintenance of bones and teeth.

5.1 Pharmacodynamic properties and Pharmacokinetic properties
- Mechanism of action: Magnesium contributes to normal energy-yielding metabolism, normal electrolyte balance, and the maintenance of normal muscle and nervous system function. Calcium and phosphorus contribute to the development and maintenance of bones and teeth.
- Magnesium is absorbed from the small intestine after oral doses. Around one-third of magnesium is absorbed via the small intestine, but this fraction increases if magnesium intake decreases. In plasma, about 25 to 30% of magnesium is protein bound. Parenteral magnesium salts are excreted mainly in the urine, and oral doses are eliminated in the urine (absorbed fraction) and the faeces (unabsorbed fraction). Small amounts are distributed into breast milk. Magnesium crosses the placenta.
- Calcium is absorbed mainly from the small intestine by active transport and passive diffusion. About one-third of ingested calcium is absorbed although this can vary depending upon dietary factory and the state of the small intestine; also absorption is increased in calcium deficiency during periods of high physiological requirement such as during childhood or pregnancy and lactation. Calcitriol, a metabolite of vitamin D, enhances the active phase of absorption. Excess calcium is mainly excreted renally. Unabsorbed calcium is eliminated in the faeces, together with that secreted in the bile and pancreatic juice. Minor amounts are lost in sweat, skin, hair and nails. Calcium crosses the placenta and is distributed into breast milk.
- Around two-thirds of ingested phosphate is absorbed from the gastrointestinal tract. Excess phosphate is mainly excreted in the urine, the remainder being excreted in the faeces.

5.2 Preclinical safety data (Adults)
When used orally and appropriately, BIOGEN SLOW RELEASE MAGNESIUM is recognized as possibly safe.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
- Polyvinylpyrrolidone, Maize starch, Milled lactose, PVP solution, Silicon dioxide and Magnesium stearate.

6.2 Shelf Life
24 Months.

6.3 Special precautions for storage
Store in a cool, dry place at or below 25 °C. Do not use after expiry date
Keep the container tightly closed.
Protect from light.
KEEP OUT OF REACH OF CHILDREN.

6.4 Nature and contents
The container is a 175 ml / 250 ml PET container. The cap is a white plastic cap with a tamper evident seal.
Pack size: 30 / 60's.

6.5 Special precautions for disposal
No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION
Biogen
23 Stag Road
Glen Austin
South Africa
Tel: 0860 347 243
Email: info@biogen.co.za
Website: www.biogen.co.za

8. REGISTRATION NUMBER
Will be allocated by SAHPRA upon registration.

9. DATE OF REVISION OF THE TEXT
April 2023.